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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,895	07/07/2004	Robert L. Bugianesi	21013P	8858
210 7590 04/01/2008 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907				
EXAMINER ANDERSON, REBECCA L				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
04/01/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,895

Applicant(s)

BUGIANESI ET AL.

Examiner

REBECCA L. ANDERSON

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-7, 9, 21, 22, 24-28 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7, 9, 21, 22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 2, 4-7, 9, 21, 22, 24-28 and 34 are currently pending in the instant application. Claim 34 is withdrawn from consideration as being for non-elected subject matter. Claims 1, 2, 4-7, 9, 21, 22 and 24-28 are rejected.

Response to Amendment and Arguments

Applicant's arguments filed 4 September 2007 and the amendment filed 21 December 2007 have been considered and entered into the instant application.

Applicants' amendment to claim 28 and the cancellation of claim 23 has overcome the objection to the claims as missing a period. Applicants' amendment to claims 1, 2, 9 and the cancellation of claims 3, 11-13, 23 and 47 has overcome the objection to the claims as containing non-elected subject matter. Applicants' cancellation of claim 47 has overcome the obviousness type double patenting rejection.

In regards to the 35 USC 103(a) rejection, Applicants' arguments have been fully considered but they are not persuasive. Applicants' argue that there is no teaching, suggestion or motivation provided by Takeda that would lead one skilled in the art to the presently claimed invention and that the examiner has engaged in impermissible hindsight to reject the instant claims as obvious. These arguments are not persuasive as KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness (KSR, 82 USPQ2d at 1396). Additionally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning.

But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Specifically, the conclusion of obviousness is based upon the fact that WO 01/38325 provides hypoglycemic and hypolipidemic active products (abstract) such as the formula (I), page 3, which overlaps with applicants' instantly claimed product. WO 01/38325 then provides preferences towards applicants' instantly claimed invention can be seen in the preferred embodiments, such as wherein R1 is thienyl substituted with phenyl, halo or alkyl substituted with halo (page 11, page 12, page 14, page 23 and 24); X is preferably a bond (page 24); m is more preferably 1 to 2 (page 25); Y is preferably an oxygen atom (page 25); A is preferably a benzene ring (page 27); n is preferably 1 to 3 (page 27); B is seen in preferred examples as pyrrolidine (page 28); W is preferably -CH2- (page 33); R3 is preferably -OR8 wherein R8 is hydrogen (page 34). These preferences provide direction and motivation towards applicants' instantly claimed invention. The motivation would be the high expectation of preparing additional products with hypoglycemic and hypolipidemic activity within the preferred embodiments of the prior art reference. The 35 USC 103 rejection is therefore maintained.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-7, 9, 21, 22 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/38325.

Determining the scope and contents of the prior art

WO 01/38325 provides hypoglycemic and hypolipidemic active products (abstract) such as the formula (I), page 3, which overlaps with applicants' instantly claimed product. Preferences towards applicants' instantly claimed invention can be seen in the preferred embodiments, such as wherein R1 is thienyl substituted with phenyl, halo or alkyl substituted with halo (page 11, page 12, page 14, page 23 and 24);

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X is preferably a bond (page 24); m is more preferably 1 to 2 (page 25); Y is preferably an oxygen atom (page 25); A is preferably a benzene ring (page 27); n is preferably 1 to 3 (page 27); B is seen in preferred examples as pyrrolidine (page 28); W is preferably –CH₂– (page 33); R₃ is preferably –OR₈ wherein R₈ is hydrogen (page 34).

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is that while the prior art provides products which overlap with applicant's instantly claimed invention and provides preferences towards applicants instantly claimed invention, the prior art does not prepare a species within applicants' instantly claimed invention.

Resolving the level of ordinary skill in the pertinent art

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare products as instantly claimed when faced with the prior art of WO 01/38325 since WO 01/38325 provides products which overlap with applicants' instantly claimed invention and provides preferences towards applicants' instantly claimed invention. The motivation would be the high expectation of preparing additional products with hypoglycemic and hypolipidemic activity.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the

Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/
Primary Examiner, AU 1626*

27 March 2008

Rebecca Anderson
Primary Examiner
Art Unit 1626, Group 1620
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